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Declarations under Rule 4.17:

- as to applicant's entitlement to apply for and be granted a patent (Rule 4.17(ii))
- as to the applicant's entitlement to claim the priority of the earlier application (Rule 4.17(iii))

Published:

- with international search report

(88) Date of publication of the international search report:
19 July 2007

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: METHODS OF PREDICTING RESPONSIVENESS TO TREATMENT

(57) Abstract: Methods and compositions are described for predicting the responsiveness to an LFA-3-Ig fusion protein or other inhibitor of CD2/LFA-3 interaction.

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INTERNATIONAL SEARCH REPORT

International application No.

PCT/US05/39070

A. CLASSIFICATION OF SUBJECT MATTER

IPC: A61K 39/00(2006.01),39/395(2006.01),38/17(2006.01);G01N 33/53(2006.01);C07K 16/46(2006.01)
C07K 14/52(2006.01)

USPC: 435/6,7.8,40.5;424/9.1,9.8,134.1;514/12;530/350,351,387.3

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 435/6,7.8, 40.5; 424/9.1,9.8, 134.1; 514/12;530/350, 351, 387.3

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
Leukocyte Facts Information Book

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
Please See Continuation Sheet

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 20030044406 A1 (DINGIVAN) 06 March 2003 (06.03.2003), especially paragraphs [0495] and [0554].	1-28, 31
X,P	BOVENSCHEN ET AL. Explorative immunohistochemical study to evaluate the addition of a topical corticosteroid in te early phase of alefacept treatment for psoriasis. Arch. Dermatol. Res. 2007, Vol. 298, pages 457-463, especially page 457 and 463.	1-7,13-20,23,24,31
Y,P		8-12,21,22,25-28
X	GOEDKOOP ET AL. Alefacept therapy reduces the effector T-cell population in lesional psoriatic epidermis. Arch. Dermatol. Res. 2004, Vol. 295, pages 465-473, see entire document.	1-11,13,14,16-20,23,24,27,28,31
Y	KRUEGER ET AL. Anti-CD11a treatment for soriasis concurrently increases circulating Tcells and decreases plaque T-cells, consistent with inhibition of cutaneous T-cell trafficking. J. Invest. Derm. 2000, Vol. 115, page 333.	1-10,13-18,31

☐ Further documents are listed in the continuation of Box C.

☐ See patent family annex.

* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T"

later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X"

document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y"

document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&"

document member of the same patent family

Date of the actual completion of the international search

19 March 2007 (19.03.2007)

Date of mailing of the international search report

27 APR 2007

Name and mailing address of the ISA/US

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INTERNATIONAL SEARCH REPORT

International application No.

PCT/US05/39070

Box I Observations where certain claims were found unsearchable (Continuation of Item 1 of first sheet)

This international report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claim Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☐ Claim Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. ☐ Claim Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of Item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:
Please See Continuation Sheet

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☒ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.: 1-28 and 31 as drawn to a method of evaluating the level of T cells

Remark on Protest

☐
☐

The additional search fees were accompanied by the applicant's protest.

No protest accompanied the payment of additional search fees.

BOX II. OBSERVATIONS WHERE UNITY OF INVENTION IS LACKING

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1. In order for all inventions to be examined, the appropriate additional examination fees must be paid.

Group I, claim(s) 1-28 and 31, drawn to method of evaluating the level of T cells.

Group II, claim(s) 29-31, drawn to method of evaluating gene expression.

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In order for more than one species to be examined, the appropriate additional examination fees must be paid. The species are as follows:

Each gene listed in TABLE I.

The claims are deemed to correspond to the species listed above in the following manner:

Claims 29-31 are generic and, therefore, correspond to any species.

The following claim(s) are generic: 29-31.

The inventions listed as Groups I-II do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: Group I relies on evaluation of the level of T cells in the dermis and/or epidermis. It has different method steps, reagents and endpoints than the method of Group II. The method of Group II requires evaluation of gene expression and does not share a corresponding technical feature with the method of Group I for reasons above.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: Each species is a different gene, having a different sequence, function and expression pattern, and therefore they do not share corresponding special technical features.

Continuation of B. FIELDS SEARCHED Item 3:

MEDLINE, EMBASE, WEST(US PATENTS, US PREGNANT PUBLICATIONS, DERWENT), NCBI

search terms: lfa-3?, alefacept, amevive, respons?, tcell, t-cell, t cell, haider, krueger j, harding s, cd3, cd103, vla-1, cd4, cd8, dermis, epidermis, weight